

## **HAND SANITIZER- alcohol gel**

### **Medek, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

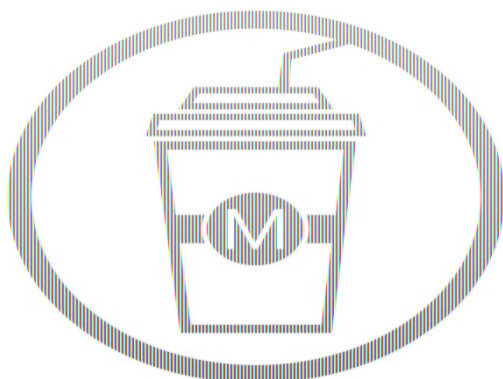
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

3785 mL NDC: 75432-001-01



## HAND SANITIZER

Alcohol Antiseptic 80%  
Topical Solution  
Hand Sanitizer  
128 oz / 3,785 ml

MADE IN MEXICO by:  
TECHDGLaboratorios Mexico S.A. de C.V  
Jalapa #125 Col. Rodriguez  
Reynosa, Tam, Mexico C.P. 88630  
Distributed by:  
Medek, LLC  
315 E. Business Hwy 83  
Alamo, TX 78516  
NDC Code: 75432-001-01

#### Drug Facts

##### Active ingredient[s]

Alcohol 80% v/v

##### Use[s]

Hand Sanitizer to help reduce bacteria th  
For use when soap and water are not ava

##### Warnings

For external use only. Flammable. Kee  
Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of ey  
of contact with eyes, rinse eyes thorough

Stop use and ask a doctor if irritation o  
signs of a serious condition.

Keep out of reach of children. If swalle  
contact a Poison Control Center right aw

##### Directions

- Place enough product on hands to cov  
together until dry.
- Supervise children under 6 years of ag  
to avoid swallowing.

##### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat abc

Inactive ingredients glycerin, hydrog

3785 mL NDC: 75432-001-02



## HAND SANITIZER

Alcohol Antiseptic 80%  
Topical Solution  
128 oz / 3,785 ml

MADE IN MEXICO by:  
Grupo Plast-Y-Kosas, S.A. de C.V  
Puebla #105 Col. Rodriguez  
Reynosa, Tam, Mexico C.P. 88630  
NDC Code: 77797-001-01

Distributed by:  
Medek, LLC  
315 E. Business Hwy 83  
Alamo, TX 78516  
(956) 800-4366  
NDC Code: 75432-001-02

### Drug Facts

#### *Active ingredient[s]*

Alcohol 80% v/v

#### *Use[s]*

Hand Sanitizer to help reduce bacteria th  
For use when soap and water are not ava

#### *Warnings*

For external use only. Flammable. Kee  
Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of ey  
of contact with eyes, rinse eyes thorough

Stop use and ask a doctor if irritation o  
signs of a serious condition.

Keep out of reach of children. If swalle  
contact a Poison Control Center right aw

#### *Directions*

- Place enough product on hands to cov  
together until dry.
- Supervise children under 6 years of ag  
to avoid swallowing.

#### *Other information*

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat abc

*Inactive ingredients* glycerin, hydrog

3785 mL NDC: 75432-001-03



**Jalisco Paper Inc.**  
Restaurant Supplies Distributor

**HAND SANITIZER**

Alcohol Antiseptic 80%  
Topical Solution  
Hand Sanitizer  
128 oz / 3,785 ml

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**MADE IN MEXICO** by:  
Grupo Plast-Y-Kosas, S.A. de C.V  
Puebla #105 Col. Rodriguez  
Reynosa, Tam, Mexico C.P. 88630

**Distributed by:**  
Medek, LLC  
315 E. Business Hwy 83  
Alamo, TX 78516  
(956) 800-4366  
**NDC Code: 75432-001-03**

**Drug Facts**

*Active ingredient[s]*

Alcohol 80% v/v

*Use[s]*

Hand Sanitizer to help reduce bacteria  
For use when soap and water are not available

*Warnings*

For external use only. Flammable. Keep away from heat and flame.

**Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of reach of children. Avoid contact with eyes, rinse eyes thoroughly if contact occurs.

Stop use and ask a doctor if irritation persists or if you experience signs of a serious condition.

Keep out of reach of children. If swallowed, contact a Poison Control Center right away for more information.

*Directions*

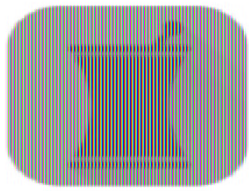
- Place enough product on hands to cover all surfaces together until dry.
- Supervise children under 6 years of age to avoid swallowing.

*Other information*

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat

*Inactive ingredients* glycerin, hydroxyethylcellulose, propylparaben, sodium benzoate, and sodium hydroxide

250 mL NDC: 75432-001-04



**O.K.**  
**PHARMACY**

**In God We Trust**

## **HAND SANITIZER**

Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer

8 oz / 250 ml

**MADE IN MEXICO** by:

Grupo Plast-Y-Kosas, S.A. de C.V

Puebla #105 Col. Rodriguez

Reynosa, Tam, Mexico C.P. 88630

**NDC Code: 77797-001-03**

Distributed by:

Medek, LLC

315 E. Business Hwy 83

Alamo, TX 78516

(956) 800-4366

**NDC Code: 75432-001-04**

### **Drug Facts**

#### *Active ingredient[s]*

Alcohol 80% v/v

#### *Use[s]*

Hand Sanitizer to help reduce bacteria th  
For use when soap and water are not ava

#### *Warnings*

For external use only. Flammable. Kee

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of ey  
of contact with eyes, rinse eyes thorough

Stop use and ask a doctor if irritation o  
signs of a serious condition.

Keep out of reach of children. If swalle  
contact a Poison Control Center right aw

#### *Directions*

- Place enough product on hands to cov  
together until dry.
- Supervise children under 6 years of ag  
to avoid swallowing.

#### *Other information*

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat abc

*Inactive ingredients* glycerin, hydrog

19000 mL NDC: 75432-001-05



# HAND SANITIZER

Alcohol Antiseptic 75%  
 Topical Solution  
 Hand Sanitizer  
 5 gal / 19 L

MADE IN MEXICO by:

Zurich Adhesivos y Ceras, S.A. de C.V.  
 Priv. San Antonio No. 410 Col Chipilo  
 San Gregorio Atzompa, PUE CP 74325

NDC Code: 77891-001-01

Distributed by:

Medek, LLC  
 315 E. Business Hwy 83  
 Alamo, TX 78516  
 (956) 800-4366

NDC Code: 75432-001-05

## Drug Facts

### Active ingredient[s]

Ethyl Alcohol 70% v/v

Isopropyl Alcohol 5% v/v

### Use[s]

Hand Sanitizer to help reduce bacteria th  
 For use when soap and water are not ava

### Warnings

For external use only. Flammable. Kee

Do not use

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- on open skin wounds

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### Directions

- Place enough product on hands to cov  
 together until dry.
- Supervise children under 6 years of a  
 to avoid swallowing.

### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat abc

Inactive ingredients glycerin, hydrog

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75432-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75432-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
2	NDC:75432-001-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
3	NDC:75432-001-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
4	NDC:75432-001-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	
5	NDC:75432-001-05	19000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2020	

**Labeler** - Medek, LLC (055524072)

### Establishment

Name	Address	ID/FEI	Business Operations
Medek, LLC		055524072	manufacture(75432-001)

Revised: 5/2020

Medek, LLC